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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,667	01/25/2002	Scott Smith	760-12 DIV	4339

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EXAMINER

AFTERGUT, JEFF H

ART UNIT	PAPER NUMBER
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1733

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,667

Applicant(s)

SMITH, SCOTT

Examiner

Jeff H. Aftergut

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other:

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Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 8, 16, 17, and 23 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cox et al (US 5,824,040).

Cox et al suggested that it was known at the time the invention was made to form a stent graft 71 assembly by first attaching a series of diamond shaped elements 73 to a strip of liner material 75 via a sewing operation, see Figure 5E. Cox et al suggested this planar ribbon was then wound over a mandrel 77 (helically) of the desired size and adjacent edges of the ribbon

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were sewn to each other or otherwise permanently joined together. See column 12, lines 19-55, Figure 5E.

While it is believed that the reference to Cox et al anticipated the claims as presented for forming the stent graft (the diamond shaped elements 73 being the stent component and the liner material 75 being the graft material, the reference never expressly stated which components were used to make up the stent and which components were used to make up the graft of the stent graft assembly. However, those skilled in the art of making a stent graft assembly would have readily appreciated that the wire, diamond shaped component 73 was the stent and that the strip material 75 was the graft material in the operation. Such would have been self-apparent as the stent material typically is a wire component which is assembled in tubular form to reinforce a vein or artery. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the processing of Cox et al to form a stent graft assembly wherein the stent component was formed from the wire reinforcing materials and the graft component was provided as a continuous tubular member for the same.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 1-9, 11-24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (US 5,824,040) in view of either one of Shannon et al (5,928,279) or Brauker et al (6,517,571).

Cox et al is discussed in detail above. The reference failed to expressly state that the wire component was the stent material and that the tape and/or strip material was the graft material. However, in the art of stent grafts, it was known at the time the invention was made to incorporate a wire component for the stent as well as a plastic (polyethylene terephthalate) as the graft component in the manufacture of a stent graft. Additionally, it was well known to embed the stent component within two layers of graft component material. Such is evidenced by Shannon et al as well as Brauker et al. More specifically, Shannon et al suggested that those skilled in the art would have disposed a stent component 14 formed of wire between two graft components 12 and 16 (where the graft components are made of ptfe). Such was a desirable arrangement for the stent graft as it would have presented a smooth interior and exterior surface for the stent graft assembly thus making insertion and retention in the body easier. Brauker et al (Figure 8C) suggested that it was known to dispose stent material 80 between an inner and outer sheet of graft material 81 formed from ptfe. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the materials of either one of Shannon et al or Brauker et al in the operation of Cox et al as such would have been recognized as conventional materials utilized by the ordinary artisan in the course of manufacturing a stent graft. Additionally, to provide the stent material such that it was encapsulated between the graft materials in strip form prior to winding would have been obvious to the ordinary artisan as: (1) Cox et al provided the completed assembly prior to winding the assembly about the mandrel,

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and; (2) the references to Shannon et al or Brauker et al suggested that in a stent graft assembly the stent materials would have been embedded between two graft materials. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the techniques of Shannon et al or Brauker et al in the operation of Cox et al to form a stent graft assembly.

With respect to claims 2-4, 12-13, 18-19, note that the reference to Shannon et al or Brauker et al suggested that one skilled in the art at the time the invention was made would have provided graft material on either side of the stent material wherein one bonded the graft material in the regions which were open in the stent layer. Regarding claims 5, 11, and 20, note that the reference to Shannon et al or Brauker et al made it clear that those skilled in the art would have employed a film of ptfe as the graft material in the operation. The reference clearly suggested non-textile materials for the graft material. regarding claims 6-7, 14-15, 21 and 22, the reference to Cox et al clearly envisioned the winding of the material about the mandrel in the formation of the stent graft and the assembly of the edges of the edges of the strip wound upon the mandrel. Note that the winding must either be overlapped and bonded at the edges, or abutted and joined at the abutting edges of the material to make the tubular structure and one skilled in the art would have readily understood that either technique would have been suitable for forming the stent graft. Regarding claim 10, note that the stent material of Shannon et al and Brauker et al was clearly defined as a wire material. regarding claim 16, note that Cox et al clearly suggested that the material would have been wound into a tubular stent graft material. regarding claims 23 and 24, the reference suggested that one skilled in the art would have employed linked diamond shaped wires (Cox) for the stent assembly. Regarding claim 26, note that Shannon et al or

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Brauker et al suggested lamination of the two graft materials with the stent material disposed there between and one skilled in the art would have understood that the graft material in planar form would have been laminated together with the stent material disposed there between prior to winding in Cox et al.

6. Claims 10 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as set forth above in paragraph 7 further taken with Martin et al (6,361,637).

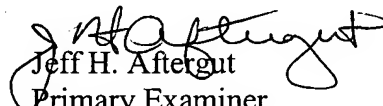
The references as set forth above in paragraph 7 suggested the overall arrangement for the stent graft, however they failed to teach that the stent material would have been disposed in an undulated configuration as well as that the stent wire material would have been formed from nitinol. However, in the art of making a stent graft assembly, it was known to provide the stent component as an undulated wire which was formed from nitinol as evidenced by Martin et al, see Figures 14A-14F for Martin et al, column 9, lines 17-column 10, line 5 for the undulated configuration of the stent component and column 10, lines 32-35 for the use of nitinol for the wire component. It should be noted that in Martin et al (as was the case for also Shannon et al and Brauker et al) the stent component in Martin et al was disposed between an inner graft 4 and an outer graft member 8 (which is a coupling member). It would have been obvious to one of ordinary skill in the art at the time the invention was made to select a suitable material for the stent component in a stent graft assembly wherein such materials would have included nitinol for the stent wire as well as providing the stent in undulating form as suggested by Martin in the operation of making a stent graft as set forth above in paragraph 7.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff H. Aftergut whose telephone number is 571-272-1212. The examiner can normally be reached on Monday-Friday 7:15-345 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.


Jeff H. Aftergut
Primary Examiner
Art Unit 1733

JHA
January 12, 2004